

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 15, 1998 list were made in April, 1998

### New Approvals

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#### ANADA No.: 200-235

Pioneer Product: 011-315  
Trade Name: Neosol Soluble Powder  
Ingredients: Neomycin Sulfate  
Sponsor: Med-Pharmex, Inc.  
Approval Date: 03/09/98  
Status: Over-the-counter  
Route: Oral  
Species: Bovine (excluding veal calves), porcine, ovine, caprine  
Drug Form: Powder  
Concentration: 227.5 g/lb and 50 g/packet  
Indications: For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.  
Tolerance: 21 CFR 556.430: the tolerances established for neomycin residues in the uncooked edible tissues of cattle, swine, sheep, and goats are 1.2 ppm in muscle, 3.6 ppm in liver, 7.2 ppm for kidney (target tissue), and 7.2 ppm in fat.  
Withdrawal: Swine and goats: 3 days; sheep: 2 days; cattle: 1day (excluding veal calves)

21CFR 520.1484

### Supplemental Approvals

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#### NADA No.: 141-034

Trade Name: GAINPRO™  
Ingredients: Bambermycins  
Sponsor: Hoechst-Roussel Vet  
Approval Date: 03/10/98  
Status: Over-the-counter  
Route: Oral  
Species: Bovine, pasture cattle (slaughter, stocker, and feeder cattle)  
Drug Form: Type A medicated article to make Type C medicated feed  
Concentration: 10 g/lb in Type A; 120 g/ton in Type C  
Indications: For increased weight gain in pasture cattle (slaughter, stocker, and feeder cattle) when fed on a free-choice basis in Vigortone's Type C medicated loose mineral feed.  
Exclusivity: 3 years

This supplemental application provides for the use of an approved Type A medicated article to make free-choice Type C medicated feeds.

21CFR 558.95

### Suitability Petition Action

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Number.: 98P-0232/CP1  
Sponsor: Virbac, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite® Spray 1.0%, Pittman-Moore, NADA 095-184, by the following characteristics: Miconazole 2% is formulated as a leave-on conditioner and Conofite® Spray 1.0% is formulated as a topical spray and a different strength.  
Action: Filed on 04/14/98.